K080360

510(k) Summary

APR - 8 2008

A. Submitted By:

Annaliza Victoria
Regulatory Affairs Specialist
Endologix, Inc.
11 Studebaker
Irvine, CA 92618
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B. Date Prepared

07 February 2008

C. Device Name:

Visiflex Dual Lumen Catheter
Classified by FDA under 21 CFR 870.1250, Catheter, Percutaneous

D. Predicate Device:

Predicate device name:	Dual Lumen Catheter
Manufacturer:	Endologix, Inc.
510(k) number:	K991601

E. Device Description:

The Visiflex Dual Lumen Catheter is designed to allow for the insertion of two guidewires into a single vessel, preventing them from crossing or entangling, and then allowing them to separately advance into different vessels. The Visiflex Dual Lumen Catheter consists of two lumens: one lumen allows the guidewire to advance along its length, and the second lumen allows separation and release of the second guidewire via two skives located 35cm apart and peeling along its length. There is a radiopaque marker near the tip of the catheter to provide visibility when placing the Visiflex Dual Lumen Catheter. There is also a radiopaque marker located at the proximal skive to aid in positioning of the catheter for advancement of a guidewire. The Visiflex Dual Lumen Catheter has an orientation feature that provides for proper positioning to aid in guidewire placement. The Visiflex Dual Lumen Catheter has a working length of 90cm and is compatible with a 9Fr introducer sheath. The proximal end of the catheter consists of a female luer connector.

F. Intended Use

The Visiflex Dual Lumen Catheter is intended for use during a two-guidewire procedure.

G. Substantial Equivalence

The Visiflex Dual Lumen Catheter is substantially equivalent to the predicate device, the Endologix Dual Lumen Catheter. The indications for use, materials, principles of operation, methods of manufacture, and performance specifications are substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Endologix, Inc.
c/o Ms. Annaliza Victoria
Regulatory Affairs Specialist
11 Studebaker
Irvine, CA 92618

APR - 8 2008

Re: K080360
Visiflex Dual Lumen Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: March 20, 2008
Received: March 20, 2008

Dear Ms. Victoria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K080360

Device Name: Visiflex Dual Lumen Catheter

Indications for Use:

For use during a two guidewire procedure

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vichney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080360